REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 34-38, 60-63 and 73-100 are pending in the subject application.

Claims 60-63 are acknowledged as being allowable by the Examiner.

Claims 1-33, 39-59 and 64-72 were previously canceled.

Claims 34-38, and 73-86 and 89-100 stand rejected under 35 U.S.C. §102. Claims 87 and 88 objected to as depending from a rejected base claim, however, the Examiner indicated that the claims would be allowable if appropriately re-written in independent form.

Claims 34 and 36 were amended to put the claims in better form. These claims also were amended in the interests of advancing prosecution by more distinctly claim Applicants' invention.

Claim 60 was amended to correct grammar and to avoid a possible antecedent basis concern.

Claim 80 was amended for clarity and to put the claim in better form. The claim also was amended in the interests of advancing prosecution by more distinctly claim Applicants' invention.

Claims 87 and 88 were written in independent form as suggested by the Examiner.

Claim 89 was amended to avoid a possible antecedent basis concern.

Claims 94, 96 and 98 were amended to correct a typo and thus put each claim in better form.

The amendments to the claims are supported by the originally filed disclosure.

35 U.S.C. §102 REJECTIONS

The Examiner rejected claims 34-38, 73-86 and 89-100 under 35 U.S.C. §102(b) as being anticipated by Steffee [USP 4,790,303]. Applicants respectfully traverse. Because claims were amended in the instant amendment, the following discussion refers to the language of the amended claims. However, only those amended features specifically relied upon to distinguish the claimed invention from the cited prior art shall be considered as being made to overcome the cited reference.

As the Federal Circuit has indicated, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). Applicants respectfully submit that it is clear from the following remarks that the above identified claims are not anticipated by Steffee.

In regards to the rejection of these claims, the Office Action asserts that the feature identified by reference numerals 50 and 52 corresponds to the arcuate implant member of the presently claimed invention; that the end portions of the arcuate members are configured to be secured to a securing mechanism identified by reference numerals 70 and 72, and that the arcuate members rotated about there own axis as they are implanted in the vertebrae. Applicants respectfully disagree.

In claim 34, Applicants claim an implantable spinal fixation system that includes an arcuate implant member. The arcuate implant member has a length that is sufficient so the arcuate implant member extends in a plane between two adjacent vertebrate. The arcuate implant member also has a cross-section that is sized so that portions of the arcuate implant member including ends thereof extend through a preformed aperture that is formed in each of the two

adjacent vertebrae. In view of the language in claim 34, the portions of the arcuate implant member including ends thereof that extend through a preformed aperture also are in this plane as well.

As indicated herein claim 34 is further amended so as to provide that the apertures formed in each of the two adjacent vertebrae define an arcuate path and that the arcuate implant member is further configured so as to correspond to the arcuate path defined by the apertures.

Claim 77, which depends from claim 34, adds the further limitations that the implantable spinal fixation system further includes a plurality of securing mechanisms one for each of the adjacent vertebrae. It is further provided that each of these securing mechanism is *configured so as to secure the securing mechanism to one of the adjacent vertebrae* and that the arcuate implant member also is configured so as to be secured to each of the plurality of securing mechanisms.

As can be seen from the following excerpts from Steffe, the elements in Steffe that correspond to reference numerals 50 and 52 are the fasteners 50, 52. The elements in Steffe that correspond to reference numerals 70 and 72 are respectively a wire cable and a connector. As also described in Steffe (see excerpts provided below), the cable 70 passes through openings 71 in the driving ends of the respective fasteners 50, 52 and the ends of the cable 20 are secured together by the connector 72.

As described in Steffe (see excerpts provided below and see also Figures 1-4), each of the fasteners 50, 52 is inserted between the fibrocartilaginous disk 60b and the surface 22a of the bone portion 22. The pointed end 62 of one curved fastener 50 is driven through the surface 22a, through the bone portion 22, through the entire thickness of the bone graft 24 and into the other bone portion 26. Also, the pointed end 66 of the other fastener 52 is similarly driven in an opposite direction entirely through one portion 26, through the entire bone graft and into the other bone portion 50. In other words, there are no apertures formed in the adjacent vertebrae through which the fasteners are driven but rather the fasteners are driven through the vertebrae much like one drives or hammers a nail into wood lumber.

The following are selected excerpts from columns 2 and 3 in Steffee.

An elongated curved fastener 10 embodying the present invention is illustrated in FIGS. 1-3. The fastener 10 includes a shank portion 12. The shank portion 12 has a pointed end 14 and at its opposite end has a driving head portion 16. A plurality of barbs 20 are spaced along the shank portion 12 and project therefrom.

The fastener 10 is preferably made from a metal material which is compatible with human tissue. Such a metal material may be titanium or surgical grade stainless steel.

The pointed end 14 of the fastener 10 is placed in contact with a surface 22a of a bone portion 22 (FIG. 5). The fastener 10 is driven into the bone portion 22. As the fastener 10 is driven into the bone portion, due to its curved configuration, it progresses along a curved path A through the bone graft 24 and into bone portion 26. The part of the shank portion 12 which extends through the bone graft 24 lies along a line B which extends generally in the direction in which the bone graft resorbs. Thus, the bone graft 24, as it resorbs, applies a force on the shank portion 12 which acts generally along the path A of the shank portion 12.

Each of the barbs 20 on the shank portion 12 have a width W (FIG. 2) which progressively increases as the barbs 20 extend in a direction along the path A opposite the direction in which the fastener is driven. Thus, the fastener 10 appears to be tapered, as viewed in FIGS. 2 and 3, from its end portion 14 and increases in width to the end portion 16 of the shank portion 12. Also, the barbs 20 have surfaces 25 which are inclined rearwardly. The surfaces 25 extend in a direction forming an acute angle with the path A along which the fastener is driven. The surfaces 25 are inclined to resist withdrawal of the fastener 10 from the bone portions 22, 36 and the bone graft 24 in a direction opposite the path A along which the fastener is driven. (Steffee, col. 2, ll. 33-68)

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The manner and the various locations in the body in which a fastener embodying the present invention may be utilized are numerous. FIGS. 4 and 5 show one specific arrangement in which a pair of fasteners 50, 52 embodying the present invention are driven into bone portions 22, 26 and bone graft 24 located therebetween. The procedure of which is described below.

The fastener 50 is inserted between the fibrocartilaginous disk 60b and surface 22a of bone portion 22. The pointed end portion 62 of the fastener

> 50 is driven through the surface 22a of the bone portion 22 by a driving force transmitted through a suitable tool, such as the driving tool 38 (FIG. 7). The pointed end portion 62 of the fastener 50 is driven through the bone portion 22 and exits the bone portion through surface 22b. The surface 22b of the bone portion extends in substantially the same direction as surface 22a. The pointed end portion 62 of the fastener 50 is then driven through the entire thickness of the bone graft 24 and into the bone portion 26 through surface 26b. The pointed end portion 62 of the fastener 50 is stopped within the bone portion 26. The barbs 64 of the fastener 50 resist movement of the fastener in a direction along the path A opposite to the direction in which the fastener was driven.
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> The end portion 66 of the fastener 52 is similarly driven in a direction opposite the direction in which fastener 50 was driven. The fastener 52 is spaced laterally from fastener 50 in the bone portions and extends completely through the bone portion 26 between surfaces 26a and 26b and the bone graft 24. The end portion 66 of the fastener 52 is stopped within the bone portion 22. The barbs 68 of the fastener 52 resist movement in a direction opposite the direction in which the fastener 52 was driven.
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> After the fasteners 50, 52 have been driven into the bone portions 22, 26 and the bone graft 24 a wire cable 70 is placed through openings 71 in the driving ends of the respective fasteners 50, 52. The wire cable 70 is made from a material compatible with human tissue, such as braided surgical grade stainless steel fibers. The ends 70a, 70b of wire cable 70 are secured together by a suitable connector 72.
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> The connector 72 is made of a material which can be deformed or crimped to frictionally engage the ends 70a, 70b of the wire cable 70 and maintain the ends of the wire cable 70 in a desired position relative to one another. The connector 72 has a portion 74 which is split extending longitudinally of the length of the connector. The ends 70a, 70b are placed within the split portion 74 in the desired relative position. The connector is then deformed or crimped by a suitable tool to maintain the wire cable in a desired tension. (Steffee, col. 3, ll. 15-65)

As described in Steffee, each of the fasteners 50, 52 includes a shank portion 12 having a plurality of barbs 20 spaced along the shank portion and projecting therefrom. The fasteners also are configured so that the shank portion decreases in width toward the pointed end so that this portion of the fastener appears to be tapered (note this is contrary to claim 74). Steffee also provides that the barbs are configured so that resist withdrawal of the fastener from the bone portions and the bone graft in a direction opposite to which the fastener was driven.

In sum, Steffe does not describe, teach or suggest an arcuate implant member "having a cross-section being sized so that portions of the arcuate implant member including ends thereof extend through a preformed aperture that is formed in each of the two adjacent vertebrae" nor describe, teach or suggest an arcuate implant member that is "configured so that it lies in a plane as it extends between the adjacent vertebrae and as the portions thereof extend through the preformed apertures" as is set forth in claim 34. Moreover, Steffee does not describe, teach or suggest an arrangement in which "the apertures formed in each of the two adjacent vertebrae define an arcuate path and where the arcuate implant member is "further configured so as to correspond to the arcuate path defined by the apertures" as set forth in as-amended claim 34.

Such configurations and arrangements of claim 34 are inconsistent with the disclosures and teachings of Steffee including the manner in which the fasteners in Steffee are to be implanted. Thus, it is respectfully submitted that claim 34 is not anticipated by Steffee.

As to claim 77 and as indicated above, Steffee describes driving the fasteners 50, 52 into the bone portions 22, 26 and the bone graft, the wire cable 70 is passed through openings 71 in the driving ends of the respective fastener.

In contrast to claim 77, in Steffe the wire cable 70 is not secured to the adjacent vertebrae and also to the fastener. Rather Steffe describes and teaches having the wire cable 70 arranged so that it is passes through openings 71 in the driving ends portions of each of the fasteners 50, 52 and then securing the ends of the cable to each other by means of the connector 72. Moreover, it is not possible for the fasteners, cable and connector structure described and shown in Steffee to be modified so as to yield an arrangement as set forth in claim 77 without necessarily destroying the intended purpose and operation of the device(s) described in Steffee as well as departing from the intended method and flow of the method described in Steffee.

Further, in the methodology disclosed in Steffe each fastener 50, 52 is driven through one of the bone portions, through the bone graft and into the other bone portion. Additionally and as more particularly illustrated in Figs. 5 and 6 of Steffee, the driving ends of each fastener must necessarily extend above or beyond the surface of bone portion. This is particularly necessary so

the wire cable 70 can be passed through the openings 71 in the fastener driving ends after the driving is completed, as is described and taught in Steffe.

Such configurations and arrangements of claim 77 are inconsistent with the disclosures and teachings of Steffee including the manner in which the fasteners in Steffee are to be implanted and secured to the vertebrae. Thus, it is respectfully submitted that claim 77 is not anticipated by Steffee.

Applicants respectfully submit that the foregoing remarks regarding claim 34 also at least apply to distinguish the spinal system as set forth in claim 36, the spinal fusion kit of claim 38, the method for stabilizing adjacent segments of a mammalian bone as set forth in claim 80, the spinal fixation system of claim 91, and the methods for stabilizing adjacent vertebrae of a mammalian spine as set forth in claims 93 or 95. Applicants also respectfully submit that the foregoing additional remarks regarding claim 77 also apply at least apply to distinguish the spinal fixation system of claim 91, and the method for stabilizing adjacent vertebrae of a mammalian spine as set forth in claim 93. Also, each of claims 35, 37, 73-79, 81-90, 92, 94, and 96-100, depend from one of the foregoing independent claims. Thus, each of these claims is considered to be allowable because it depends from a base claim that is considered to be allowable. This shall not be construed as an admission that any of these claims is not otherwise patentable over Steffee.

For example, there is no description anywhere in Steffee of rotating an arcuate member of a size sufficient to extend in a plane between the two adjacent vertebrate from a first position to a second position such as that provided in claims 95-99 of the present invention. Such a concept is completely different from that described in Steffee, which describes driving two curved shaped fasteners 50,52 through one of the adjacent vertebrae and into the other adjacent vertebrae, passing a cable 70 through an opening in the ends of the fasteners 50, 52 that project above the vertebrae and securing the ends of the cable 70 to each other by a connector 72. Such a construction does not in any way or fashion describe the arcuate member of the present invention. Furthermore, there is no structure described in Steffee nor is there also any method

described in Steffe that would correspond to the localizing and securing steps of claim 97 nor the structures described in such steps.

Also, for example, claim 94 provides that said securing includes threadably securing said each end of the plurality of securing members respectively to said one of the adjacent vertebrae. As can be seen from above excerpts from Steffee, there is no description, teaching or suggestion anywhere in Steffee of threadably securing the cable 70 to the vertebrae. Applicants would note that Steffee also does not describe or teach threadably securing the fasteners to the vertebrae.

In sum, the system, apparatus and methodology disclosed and taught in Steffee differs in numerous respects from the methodology, kits and systems claimed by Applicants. Thus, it can hardly be said that Steffee discloses the methods, kits and systems claimed by Applicants. Further, the systems, apparatuses and methods disclosed in Steffee cannot be modified so as to yield the methods, systems, and kits of the present invention without destroying the intent purpose and function of the inventions disclosed in Steffee.

In deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify *corresponding elements* disclosed in the allegedly anticipating reference (emphasis added, citations in support omitted). *Lindemann Maschinenfabrik GMBM v. American Hoist and Derrick Company et al.*, 730 F. 2d 1452, 221 USPQ 481,485 (Fed. Cir. 1984). In concluding that the `770 Patent did not anticipate the claims, the Federal Circuit in *Lindemann Maschinenfabrik GMBM v. American Hoist and Derrick Company et al.*, at 221 USPQ 485-486, further provides that:

> The `770 patent discloses an entirely different device, composed of parts distinct from those of the claimed invention, and operating in a different way to process different materials differently. Thus, there is no possible question of anticipation by equivalents. Citations omitted.

It is clear from the foregoing remarks, that the allegedly corresponding elements disclosed in Steffe (*e.g.*, reference numerals 50, 52, 70, 72) do not in fact correspond to the elements of the claimed invention. It also is clear that the methodologies described in Steffe function and operate in a different manner from that of the claimed invention. Thus, there can be no disclosure or teaching in Steffe of Applicants' invention.

While the within rejection is under §102, Applicants would note that as to 35. U.S.C. §103, the the Federal circuit, has indicated that a 35 U.S.C. §103 rejection based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in a reference, is not proper and the prima facie case of obviousness cannot be properly made. In short there would be no technological motivation for engaging in the modification or change. To the contrary, there would be a disincentive. *In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984). In the present case it is clear that if the device and methods described in Steffee were modified so as to yield the claimed systems, kit or methods such a modification would destroy the intent, purpose or function of the device, systems and methods as taught by Steffee.

It is respectfully submitted that for the foregoing reasons, claims 34-38, 73-86 and 89-100 are patentable over the cited reference and thus, satisfy the requirements of 35 U.S.C. §102(b). Therefore, these claims are allowable.

CLAIMS 87-88

In the above-referenced Office Action, claims 87-88 were objected to as being dependent upon a rejected base claim. It also was provided in the above-referenced Office Action, however, that these claims would be allowable if rewritten in independent form to include all the limitations of the base claim and any intervening claim(s).

Claims 87 and 88 were re-written in the foregoing amendment so as to be in independent form and the intervening claim(s). Thus, claims 87 and 88 are considered to be allowable.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Because the total number of claims and/or the total number of independent claims post amendment now exceed the highest number previously paid for, authorization is provided herewith to charge the below-identified deposit account for the required additional fees. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,
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